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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

TAMARA CARTER and DAVID CARTER,

Plaintiffs,

vs.

JOHNSON & JOHNSON; ETHICON, INC.; and ETHICON LLC,

Case No. 2:20-cv-01232-KJD-VCF

JOINT PRETRIAL ORDER

Defendants.

After pretrial proceeding in this case,

IT IS ORDERED:

I. NATURE OF ACTION

This is a products liability action involving two prescription medical devices – Prolift and TVT. On July 23, 2010, at St. Rose Dominican Hospital – San Martin Campus in Las Vegas, Nevada, Dr. Gregory Hsieh implanted a Prolift device for Tamara Carter's posterior pelvic prolapse and a TVT mid-urethral sling for Mrs. Carter's stress urinary incontinence ("SUI"). Mrs. Carter alleges that these medical devices caused her injuries and that Defendants are liable under claims of strict liability for failure to warn and design defect. Her husband David Carter raises a loss of consortium claim. Additionally, Plaintiffs claim that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore, an award of punitive damages is appropriate. Defendants deny Plaintiffs' allegations and assert that Prolift and TVT were state of the art at the time of implant, Mrs. Carter's alleged injuries pre-dated her surgery on July 23, 2010, Mrs. Carter assumed the risks, and Mrs. Carter's actions contributed to her injuries.[1]

A. PLAINTIFFS' CONTENTIONS

1. The Prolift Device

[1] Plaintiffs assert that the only affirmative defense permitted in this case is assumption of risk. *See Young's Mach. Co. v. Long,* 100 Nev. 692, 694 (1984).

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The Prolift was designed to treat pelvic organ prolapse ("POP"). Prolapse occurs when the body's support for the bladder, rectum, intestine and/or uterus is weakened, allowing an organ to bulge/drop into the vagina. The Prolift procedure involves the insertion of a massive mesh implant with large mesh arms that extend down into the depths of the pelvis, ostensibly to provide support for the prolapsed organ(s). Because Mrs. Carter suffered from rectocele (rectal prolapse), her surgeon chose to implant the Prolift posteriorly into the vagina. As designed by Ethicon, the mesh implants were held in place by the insertion of mesh arms attached as part of the implants. These arms, as well as the remainder of the mesh implants, are implanted through the TVM technique developed by Ethicon and marketed by Ethicon as part of the Prolift kit. The TVM technique, short for transvaginal mesh, required the introduction of the mesh into the body through the vagina and then pulling the mesh arms and remainder of the implant through the vagina and into place in the spaces between the vagina and the bladder or the rectum. This technique, marketed as an "innovative" and "tension free" technique, held the implant in place by leaving the arms extending through many different anatomical structures within the pelvis, including anatomical areas that had no defect or weakness whatsoever, by use of large, sharp trocars. The mesh arms were then pulled out through skin incisions, where they were trimmed at the level of the skin.

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Ethicon ignored safety and efficacy concerns with the Prolift when bringing it to market, as Ethicon's goal was to get the device to market as quickly as possible. That is, Ethicon was pursuing what it perceived to be a market of hundreds of millions of dollars and was in a race since its competitor American Medical Systems ("AMS") was getting to the market first with similar competitive prolapse mesh kits, known as the Apogee and Perigee. In its rush to take this product to market, Ethicon failed to properly test this TVM technique, with this size and shape of implant, actually implanted through the vagina, a clean-contaminated environment, leaving the implant contaminated after it was in the body.

Very soon after the Prolift was released, Ethicon began to accumulate data and information provided by surgeons regarding Prolift mesh and procedure complications – including particularly intractable, untreatable pain and dyspareunia (painful sexual intercourse). In addition, Ethicon also began to accumulate more data regarding erosions and exposures of mesh after implantation as well as contraction, bunching, and roping of the mesh leading to further pain and other remote complications many years after implantation. This led Ethicon to develop and market the Prolift +M – a product Defendants billed as a more "natural" and thus a safer alternative. The Prolift +M was the same Prolift procedure and instruments (trocars), but the mesh used was partially absorbable. (+M signifies the

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Monocryl component – which was absorbable.) The goal of the Prolift +M was to leave less mesh material, with larger pores and lighter weight, in a woman's body, and consequently reduce the inflammatory reaction, resulting scarring, and other complications. Ultimately, Ethicon ceased marketing and selling the Prolift and Prolift +M. Ethicon also changed the warnings (indications) for the Gynemesh PS (Prolift's predecessor) to indicate for abdominal placement only, not vaginally any longer, as of September 1, 2012.

2. The TVT Device

The TVT mesh device was designed to treat stress urinary incontinence in women. Like the Prolift mesh, the TVT mesh is made of polypropylene, with other additives, plus tools to aid with implantation. The mesh is mechanically cut from large sheets of polypropylene and, thus, the mesh frays and has sharp edges, and pieces of the mesh fall off when tension is applied to the mesh. It ropes, curls, and deforms when any amount of tension is applied. According to Ethicon's own internal documents, the mesh was initially designed as a hernia mesh in the 1970s and is a heavyweight mesh with small pores. The heavy nature of the mesh combined with the defects in the design of the TVT – including the fact that it degrades, deforms, frays, ropes, curls and has sharp edges – lead to excessive inflammation, scarring, and contraction of the mesh when implanted. Like the Prolift, the effect of these defects are magnified because the TVT is implanted

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through a woman's vagina and into her pelvic tissue. Because the mesh and the pelvic tissue surrounding it become stiff and brittle over time, the TVT causes injuries including, but not limited to, chronic pain syndrome, pain with sex, urinary dysfunction, and erosions into tissues and organs. Ethicon experienced excessive complications in hernia patients with the old construction mesh it chose for the TVT, and its own consultants warned that the use of the heavyweight, small-pore mesh would increase the foreign body response, scarring, and complications if used anywhere in the body. Nevertheless, Ethicon has continued to use the old construction mesh in the TVT.

The early studies Ethicon relied on for its claims that the TVT is safe and effective were performed by the inventor and other paid consultants with a personal financial stake in the outcome of the studies, and Ethicon never verified the data from the studies. Ethicon, itself, never studied the TVT in women before launching the product onto the market and never asked independent investigators to do so either.

Following launch, adverse event reports related to the TVT began to pour in, including but not limited to complaints of erosions into nearby organs, pain including chronic, debilitating pain, urinary dysfunction, bleeding, dyspareunia, sexual dysfunction, and other injuries. Ethicon admits that all of these complications were known to it at the time the TVT was launched. Yet, many of

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these complications were downplayed in Ethicon's published studies, instructions for use, marketing materials, and sales aids to physicians and patients.

It is undisputed that the mesh used in the TVT product is the "old construction" hernia mesh developed by Ethicon in 1974. It is also undisputed that Ethicon continued to use this heavyweight, small pore mesh even after Ethicon had access to safer mesh and even though Ethicon knew that the mesh construction caused it to rope, curl, deform, lose particles and to have sharp, frayed edges. By the early 2000s, Ethicon had access to lighter weight, larger pore, heat sealed meshes that were much safer for patients, yet for marketing and business reasons they continued selling the old construction mesh in the TVT.

3. Mrs. Carter's Implants and Injuries

On July 23, 2010, Mrs. Carter underwent surgery, during which Dr. Hsieh implanted a Prolift to treat her posterior pelvic organ prolapse and a TVT to treat her SUI. At that time, the product labels warned only of general surgical complications, but not novel Prolift and TVT-related complications (as discussed in greater detail below). At the time that Dr. Hsieh implanted the devices into Mrs. Carter, he was unaware that the Prolift mesh could rope or curl or that there could be a chronic foreign body reaction from the mesh in the Prolift and TVT.

Dr. Hsieh has testified that he relied on the devices' instructions for use and passed those risks along to his patients.

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Following the implantation of the Prolift and TVT devices, Mrs. Carter experienced multiple mesh erosions, chronic pain, and other injuries. On October 31, 2011, Mrs. Carter returned to Dr. Hsieh and was found to have an erosion at the posterior vaginal wall, which was tender to palpation. On November 30, 2011, Dr. Hsieh trimmed the mesh exposure in the office. On December 21, 2011, Mrs. Carter returned to Dr. Hsieh with complaints of heavy vaginal bleeding after sex and feeling mesh in the vagina. On exam, mesh erosion was again noted. As a result, on January 6, 2012, Dr. Hsieh took Mrs. Carter back to the operating room and performed a mesh extrusion repair. In May of 2012, Mrs. Carter presented with complaints of mesh exposure, vaginal pain, and bleeding. An exam demonstrated a mesh exposure on the posterior vaginal wall. Consequently, Mrs. Carter again underwent surgery to remove to portions of the mesh on September 27, 2012. Thereafter, an additional mesh erosion was noted on February 6, 2013. Unfortunately, her chronic pelvic pain persisted, and another mesh exposure was seen on October 31, 2014, which required an additional mesh excision surgery on January 6, 2015. Mrs. Carter was returned to the operating room to repair another area of exposed posterior mesh on May 26, 2015. Mrs. Carter had an additional surgical procedure on July 23, 2015 for the treatment of her recurrent SUI with an autologous fascial sling.

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At the present time, portions of the Prolift and TVT mesh remain in Mrs. Carter's pelvic musculature and currently cause, and will continue to cause, chronic pain and other injuries. Mrs. Carter continues to suffer severe pain and complications from her Prolift and TVT implants, including, but not limited to, pelvic pain, pelvic floor myalgia, dyspareunia, and emotional injuries, which will likely be lifelong.

Regarding Plaintiffs' claims in this case, they assert the following causes of action:

1. Design Defect

Plaintiffs will present evidence of numerous design defects that rendered the Prolift and TVT unreasonably dangerous for their intended uses, including, but not limited to, the following:

1. The polypropylene material used in the mesh causes a chronic foreign body reaction that leads to adverse reactions and injuries;

2. The mesh degrades and fragments over time;

3. The mesh "creeps" or gradually elongates and deforms when placed under tension within the body;

4. The mesh causes scar plate formation;

5. The Prolift and TVT as designed cannot be safely placed for several reasons, including:

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a. The placement occurs through a "clean contaminated" space, meaning the devices are inserted into and through an area of the body with high levels of bacteria that adhere to the mesh, causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

b. The procedure requires tensioning of the mesh at placement; and

c. There is no way to place the device without causing an intense foreign body reaction and fibrotic bridging in the pelvis;[2]

6. There is no safe, effective procedure for removal of the Prolift and TVT when needed and the Prolift mesh cannot be entirely removed;

7. The mesh is small pore;

8. The mesh is heavyweight;

9. The mesh is too rigid/inflexible/inelastic;

10. The mesh shrinks and contracts following placement;

11. The mesh causes vaginal erosion, extrusion, inflammation, and infection;

12. The mesh causes chronic tissue inflammation;

[2] Additionally, the Prolift as designed cannot be safely placed because the placement procedure is "blind" and the arms of the mesh are placed with trocars through the muscles.

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13. The mesh entraps the nerves; and

14. The mesh causes chronic, permanent, debilitating pain.

Plaintiffs will also present evidence that these design defects existed at the time the Prolift and TVT devices left Defendants' control, that Defendants failed to adequately test and/or perform appropriate clinical studies on the devices before marketing and selling it for implantation in human beings, that the Prolift and TVT devices were used in a manner which was reasonably foreseeable by Defendants, and that the defective design of the Prolift and TVT caused Plaintiffs' injuries and damages.

Lastly, although safer alternative design is not a required element under Nevada law, at the time the Prolift device was implanted in Mrs. Carter the following safer alternative designs and procedures existed:

1. Abdominally placed mesh;

2. Colporrhaphy and native tissue repair;

3. Sacrocolpopexy;

4. Larger pore, lighter weight mesh;

5. Mesh without arms and without use of trocars.

At the time the TVT device was implanted in Mrs. Carter, the following safer alternative designs and procedures existed:

1. Surgical repairs using sutures instead of mesh (e.g., Burch procedure);

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2. Autologous fascia slings; and

3. Allograft slings.

2. Failure to Warn

Plaintiffs will present evidence that Defendants failed to adequately warn Plaintiff and her treating physicians of the dangers and risks caused by and/or associated with the Prolift and TVT that were known or should have been known to Defendants, including the following:

1. pelvic pain;

2. vaginal pain;

3. groin pain;

4. pelvic pain syndrome;

5. painful intercourse;

6. mesh banding and hardening;

7. recurrent prolapse;

8. degradation, fragmentation and/or "creep;"

9. excessive contraction and shrinking;

10. balling and bunching of mesh;

11. mesh folding;

12. vaginal shortening;

13. inability to remove the mesh entirely, and potential need for multiple

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removal surgeries;

14. increased inflammatory tissue response;

15. permanent, chronic, debilitating pain;

16. the rate and manner of mesh erosion;

17. that devices should not be placed in sexually active women;

18. use of the devices exposes patients to a greater risk of future surgeries;

19. the lack of elasticity of the mesh;

20. the complications and consequences of the foreign body reaction caused by the mesh; and

21. the Prolift was rushed to market against the wishes of Defendants' consultants and employees.

Defendants further failed to warn patients and physicians of the lack of efficacy of the Prolift device implanted in Plaintiff. More specifically, Defendants failed to warn that treatment of pelvic organ prolapse with Prolift is no more effective than feasible available alternatives and exposes patients to a greater risk of adverse events/injuries than those alternatives.

Lastly, Plaintiffs will present evidence that Plaintiffs' injuries and damages caused by the Prolift and TVT were foreseeable to Defendants, and that Defendants' inadequate warnings, information, and instructions proximately caused Plaintiffs' injuries and damages, as Mrs. Carter's implanting physician

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would have been able to give proper informed consent to Mrs. Carter, who would not have undergone implantation of the Prolift and TVT if informed of any of the dangers and risks associated with the devices.

3. Loss of Consortium

Plaintiff David Carter asserts a loss of consortium claim, as the injuries caused by Defendants' products have deeply impaired all facets of his relationship with his wife. Plaintiffs will present evidence of Plaintiff David Carter's loss of consortium at trial.

4. Punitive Damages

In general, Plaintiffs' punitive damages claim is based on the following categories of conduct by Defendants evidencing deliberate disregard for the rights and safety of others:

1. Defendants failed to perform multiple necessary tests prior to selling the Prolift and TVT devices;

2. Multiple physicians, consultants, and employees warned Defendants of design defects in and complications and injuries caused by the Prolift and TVT, and Defendants chose to ignore those warnings and sell the products without properly testing or studying them first;

3. Multiple physicians, consultants, and employees warned Defendants of the need for a different mesh material to be used in the Prolift and TVT

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prior to and after being placed on the market, and Defendants chose to ignore those warnings and sell the products without properly testing or studying them first;

4. Employees and consultants of Defendants warned of the need to add warnings to the Instructions for Use ("IFU") and patient brochure, and Defendants chose not to do so;

5. Defendants blatantly and knowingly misled and made false statements to physicians and the public about the efficacy of the devices and complications caused by the devices, as well as concealed information about the efficacy of the devices and complications caused by the devices from physicians and the public, resulting in injury to thousands of women, including Plaintiff;

6. Defendants chose not to warn physicians of numerous, chronic, debilitating complications and injuries caused by the Prolift and TVT devices despite knowing the devices caused those complications and injuries;

7. Defendants placed profits over patient safety, resulting in serious injury to Plaintiff and thousands of other women;

8. Despite Defendants' awareness of the numerous defects in the Prolift and TVT devices, and the serious injuries caused to women such as Plaintiff

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by the devices, Defendants continued to sell the Prolift until 2012, when it was finally removed from the market, and continued to sell the TVT.

B. DEFENDANTS' CONTENTIONS

Defendants deny Plaintiffs' allegations. Ethicon's Prolift and TVT products are prescription medical devices that were state of the art at the time of implant, were properly designed for pelvic surgeons, like Dr. Gregory Hsieh who implanted the devices, and had adequate warnings.

There is no defect in either of these products that caused Mrs. Carter's alleged injuries. Mrs. Carter's alleged injuries pre-dated her surgery on July 23, 2010 and were exacerbated by her long history of nicotine and substance abuse, including drug seeking behavior for narcotics and pain medications. Her quality of life prior to July 23, 2010, included significant chronic pain and debilitating mental health problems.

1. The Products

a. Prolift

Prolift is a mesh device used to surgically manage pelvic organ prolapse, which is the abnormal descent or herniation of pelvic organs, such as the bladder, rectum, colon and uterus, from their normal attachment sites in the pelvis. The prolapse happens when the pelvis muscles and tissues can no longer support these organs, causing a woman to experience vaginal pressure, pelvic pain, urinary problems, bowel problems and pain with sex. Prolift is a large pore, light-weight,

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partially absorbable polypropylene mesh that is used to provide a support structure to maintain the organs in their proper anatomic position. FDA cleared the mesh used in Prolift in 2002 and the Prolift kit in May 2008. At the time of Mrs. Carter's implant in 2010, Prolift was the state of the art and within the standard of care to treat prolapse. Indeed, there was no safer mesh design for the treatment of prolapse at the time of implant.

b. TVT

TVT is a mid-urethral mesh device used to surgically manage a condition called stress urinary incontinence ("SUI"). SUI is when urine leaks out with sudden pressure on the bladder and urethra, causing the urethral sphincter muscles to open. The pressure leading to the leakage may be caused by laughing, sneezing, coughing, exercise, walking, and other activities. The TVT device is intended to lift the urethra to its proper anatomic place. It is made from a large pore, light-weight polypropylene mesh. The procedure to implant TVT takes less than 30 minutes and can be done on an out-patient basis if done alone, without other procedures.

FDA cleared TVT for use in 1998. This device is **the** most-studied anti-incontinence devices in the world. Professional organizations comprised of pelvic surgeons continue to find that mid-urethral slings, such as TVT, are safe and effective products when used as directed. At the time of Mrs. Carter's implant, TVT was the state of the art and standard of care to surgically manage SUI. Indeed, there

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was no safer mesh design at the time of implant, and TVT continues to be available for use by pelvic surgeons.

2. Mrs. Carter's Medical History

Mrs. Carter presented to Dr. Geoffrey Hsieh, a board certified urogynocologist, in 2010 with recurrent stress and urge urinary incontinence, recurrent vaginal prolapse and vaginal wall mesh exposure from a prior surgery. She had a feeling of a vaginal mass and pressure and was concerned about the vaginal mesh exposure.

This was not Mrs. Carter's first time to seek surgical options for SUI and prolapse. Mrs. Carter's incontinence dates back to about the mid-1990s. Early records note that she had ongoing incontinence for about 8 years prior to 2002 with complaints of leakage with running, coughing or any type of exercise, complaints of urgency and waking up 4-5 times at night to void. She had tried Ditropan XL for her urgency. She also had a Grade 2 cystocele (bladder pushing down into vagina), which she felt caused her lower back pain.

Nine years before her consultation with Dr. Hsieh, on January 2, 2001, Mrs. Carter had a vaginal sling procedure where two bone anchors were permanently affixed into her pubic bone and a sling made from Repliform was implanted for SUI management. She also had a procedure using sutures to repair her cystocele. Her admission records show that she was on multiple medications including Methadone

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130 mg bid, Tegretol, Neurontin and Celexa and was attending a methadone clinic daily (treatment for drug addiction). The January 2001 surgery was not successful. Mrs. Carter complained of chronic pelvic pain, pain with sex and recurrent SUI.

Three months later, in April 2002, Mrs. Carter had a second surgery. She had a take down of the sling and another procedure permanently affixing two more bone anchors and implanting another Repliform sling. In addition, Prolene sutures were inserted to allow future "change and re-fit size of the sling." Five days after surgery, Mrs. Carter presented to the ER with wound separation, bleeding, and pain. Mrs. Carter was noted to be on the DEA list for receiving narcotics from multiple physicians. She had reportedly removed the suprapubic catheter herself earlier in the day due to discomfort. She was given pain medicine. Records indicate that Mrs. Carter was argumentative with the staff. She was counseled against smoking due to her wound complication. She left the hospital prior to final discharge instructions.

That April 2002 anti-incontinence procedure was unsuccessful. Mrs. Carter continued to suffer chronic pelvic pain, pain with sex, and recurrent SUI. In June 2002, Mrs. Carter presented to Dr. Victor Grigoriev, a board certified urologist, for UTI. She complained of severe pain when urinating and stabbing pain in the urethra. His initial impression was a full take down of the sling and the Prolene sutures. He also found that she had a rectocele (rectum pushing into vagina).

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Mrs. Carter's rectocele is related to her three pregnancies, chronic cough from nicotine abuse, and long-term opioid abuse. Mrs. Carters' chronic opioid usage caused bowel dysfunction, which led to prolonged pressure on posterior vagina and a rectocele, which worsened over time.

In October 2002, Mrs. Carter sought a consultation from Dr. Shlomo Raz at UCLA. She reported incontinence at rest, when she stood and with coughing and sneezing that was treated with pads. She also complained of dyspareunia and rectal pain. She had chronic back pain that was significantly worse after the surgeries as well as subjective numbness and paresthesia in both legs and weakness when attempting to stand. Dr. Raz documented that Mrs. Carter "had chronic pain with persistent incontinence due to a foreign body reaction to bone anchors and Repliform sling."

On January 24, 2003, Dr. Raz removed the old sling and the Prolene sutures, but was "unable to remove the bone anchor through the bone itself." He then created his own sling with a soft Prolene mesh and used it to lift the urethra to its proper anatomic position. Pathology from the January 24, 2003 sling removal showed chronic inflammation and dense fibrosis.

One month later, Mrs. Carter returned to Dr. Grigoriev with complaints of vaginal pain and dysuria. It was noted that she had been seen earlier, had an erosion

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that would have required treatment, but she appeared "to be more concerned about legal matters, rather than trying to get better."

Dr. Grigoriev continued to provide treatment to Mrs. Carter. In May 2003, he recommended a removal of the sling. In August 2005, Dr. Grigoriev found that Mrs. Carter had a recurrent bladder prolapse and continued to have a rectocele. She was noted to be agitated, nervous, and noncompliant in the past.

Also in 2005, Mrs. Carter had numerous visits to various doctors and ERs with continued narcotic-seeking behavior, cocaine use, and psychiatric issues. Her earliest medical records from 2000 show she received Soma, Lortab, Vicodin on the 27th and 29th from 2 other providers, which plaintiff "does not admit to," and she became "irate" when she was not prescribed another pain medication like Lortab. She gave herself self-inflicted wounds to access more pain medications in 2000. She presented to a doctor in 2005 at an "altered level of consciousness … suspected narcotics."

By the time Mrs. Carter first saw Dr. Hsieh in 2010, Mrs. Carter had long history of chronic pelvic pain, pain with sex, recurrent SUI, urge incontinence, prolapse, and three failed sling procedures with different types of mesh products. She had stopped having sexual intercourse in 2007.

In addition, Mrs. Carter's surgical history included: 3 Cesarean sections; a total abdominal hysterectomy; an abdominoplasty (a tummy tuck); surgery for right

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hip fracture with hardware (July 12, 2006); surgery for left subtrochanteric femur fracture with hardware (December 21, 2006); surgical removal of hardware in right hip (January 14, 2008); surgical removal of intramedullary hip screw (August 5, 2009); left total hip arthroplasty (January 14, 2010); multiple nose surgeries from chronic cocaine abuse.

Mrs. Carter's medical history was significant for chronic bilateral hip pain with opioid-dependency, chronic neck and back pain, chronic COPD, smoker's cough, vaginal pain, dyspareunia, dysuria, UTIs, adhesions, recurrent cystocele, rectocele, SUI, urge incontinence, irritable bowel syndrome, bowel dysfunction, hypothyroidism, ADHD, narcotic abuse, drug seeking behavior, long-standing history of cocaine abuse, septal deviation secondary to cocaine abuse, Wegener's granulomatosis, and tobacco addiction (half pack to one pack per day for over 30 years).

In addition to her surgical and medical history, Mrs. Carter's preexisting psychological history is extensive and includes depression, anxiety disorder, bipolar disorder which she has suffered from since childhood and at least 15 suicide attempts, including stabbing her own throat, overdosing on prescription medications, jumping out of a moving car. The worst attempt was when she took 90 Somas, which resulted in her being in a coma for three weeks.

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Mrs. Carter complained that her husband abused her and attempted to "poison her." When referred to a women's shelter for possible domestic violence, she refused to go. The next day, she went to the urgent care facility with a red swollen area in her right arm. She told the healthcare providers she was in an abusive relationship but was not ready yet to press any charges or call the police. She reported to her healthcare providers that she went to jail for hitting her 23 year old son, but later told her psychiatrist that she called the cops and asked to be locked up.

3. Consenting Process and 2010 Surgery

Dr. Hsieh never had the benefit of Mrs. Carter's complete medical history during his treatment and care of the patient. Based on the information provided by Mrs. Carter, diagnostic testing, and his examinations finding a symptomatic rectocele, recurrent SUI and mesh erosion, Dr. Hsieh recommended surgery. On July 23, 2010, Dr. Hsieh performed a urethrolysis (removal of scar tissue by the uretha), placement of retropubic mid-urethral sling, excision of the expose sling implanted by Dr. Raz, and placement of a posterior Prolift.

Dr. Hsieh testified that, by the time he performed his surgery in 2010, he was very knowledgeable and experienced, had placed over 1,000 slings and half as many prolapse kits. He had received additional training on mesh kits and slings like Prolift and TVT. He served as an Ethicon preceptor for about seven years and had participated in studies involving mesh. Dr. Hsieh testified that he knew that risks

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of mesh included, among other things: acute and chronic pain; dyspareunia; erosion; mesh can change once in the body; shrinkage; infection; inflammation; difficulty of removal; foreign body reaction; urinary problems; and the potential need for revision; and he informed patients like Mrs. Carter of these risks. Dr. Hsieh also understood the risks of non-mesh surgical treatment options for her conditions, like chronic pain, vaginal scarring, infection, urinary problems, organ and nerve damage, wound complications, inflammation, fistulas, neuromuscular problems, recurrence, foreign body response to suture, exposure/extrusion of sutures – and these are also the risks for mesh that were well known by 2010, along with contraction. Dr. Hsieh testified that the IFU was adequate for him. Further, Dr. Hsieh's consent forms were extensive and covered the risks of injuries Mrs. Carter claims in this lawsuit.

Dr. Hsieh testified at his deposition that he may have done a different course of treatment with complete information (prior surgeries, drug abuse), but based on the information provided by Mrs. Carter, he stands by his decision to treat her rectocele with Prolift Posterior and her SUI with TVT. Moreover, all of the experts in this case – for plaintiff and defense – admit that it was within the standard of care to treat a patient with Prolift and TVT in 2010.

4. Prolift & TVT Are Not Defective Under Nevada Law

Contrary to Plaintiffs' assertion, Prolift and TVT are not defective. There is no objective evidence supporting a failure to warn or a design defect. As discussed

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above, Dr. Hsieh knew and understood the risks of surgery with mesh and without. There is no evidence that any other warning would have changed his decision. The only thing that would have changed his decision is had Mrs. Carter disclosed her full medical history.

Likewise, while plaintiffs have designated a case specific expert on design defect, Mrs. Carter saw numerous well qualified physicians in urogynecology and urology (Dr. Hsieh, Dr. Grigoriev, Dr. Weiss, and Dr. Tenggardjaja) who had used mesh in their practices and who had treated Mrs. Carter for symptoms she believed were related to mesh. None of them testified that the mesh was defective. Further, not one single physician who removed mesh from Mrs. Carter ever saw evidence of degradation, roping, curling, or infection. Rather, Mrs. Carter's doctors attributed her complaints to other factors, including her chronic pain syndrome, nicotine, opioid, and cocaine abuse.

For example, Dr. Tenggardjaja testified at his deposition that he cannot rule out cocaine as a contributing cause to Mrs. Carter's alleged injuries. He explained that "if you use cocaine over a long period of time that can have an effect in terms of healing potential and also in terms of the vascularity in the area[.]" Mrs. Carter was using cocaine during the time she received treatment and care with Dr. Tenggardjaja. Her records document longstanding cocaine abuse. During his treatment and care of Mrs. Carter, Dr. Tenggardjaja never formed a medical opinion

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to a reasonable degree of medical certainty that mesh was a cause of Mrs. Carter's vaginal pain, pain with sex, vaginal ridging or fistula formation.

Furthermore, Mrs. Carter is a poor historian and frequently provides her doctors with inconsistent information. By way of one illustration, among many, Dr. Avi Weiss documents in his records that Mrs. Carter denied vaginal surgery prior to Dr. Raz's intervention. Mrs. Carter in fact had two prior vaginal surgeries before Dr. Raz, which she later admitted to Dr. Weiss. She denied to Dr. Weiss any further surgery after Dr. Hsieh implanted the sling. Later, she admitted that "she 'forgot' to report that [D]r. [H]sieh had removed the sling previously."

Medical records report Mrs. Carter mixing psychiatric medicine with cocaine in November 2015. Had the implanting physician known about her history with drugs, it would have made him rethink his treatment plan.

5. Loss of Consortium Claim

Mr. Carter's consortium claim lacks merit. Mr. and Mrs. Carter have had a challenging relationship, in part because of Mrs. Carter's bipolar disorder and her report of domestic abuse. Mrs. Carter stopped having sexual intercourse with her husband in 2007, three years before she had surgery with Dr. Hsieh. Her records document that sexual intercourse was unbearable because of her hip pain. Also, Mrs. Carter did have an extramarital affair in 2011, which means that she could be

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intimate, but chose not to be with her husband, which makes sense given her reports of domestic abuse.

6. Punitive Damages

Plaintiffs have insufficient evidence to support a request for punitive damages. Indeed, the MDL Court never found punitive damages warranted in the bellwether trials.

Plaintiffs assert in their section above that their punitive damages evidence consists of alleged lack of testing, placing profits over safety, and other reptilian characterizations of company conduct. FDA regulations, however, do not require absolute safety. FDA regulations do not require pre-market testing of Class 2 medical devices, like Prolift and TVT.

If the Court finds that Plaintiffs have met their substantial burden, then Defendants should be able to introduce FDA evidence to rebut a punitive damages claim. *See Hrymoc v. Ethicon, Inc.*, 467 N.J. Super. 42 (App. Div. 2021), *cert. granted*, No. 085547 (Oct. 22, 2021). Although not binding on this Court, *Hrymoc* is instructive. *Id.* (reversing the lower court's categorical exclusion of 510(k) evidence because a "complete ban on any disclosure of the 510(k)-clearance process to the jurors . . . ha[s] the clear capacity to lead to possibly unjust results" and, accordingly, reversing two trial courts' categorical exclusion of 510(k) evidence).

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In fact, numerous courts have held that compliance with federal regulations—or even a good-faith attempt at compliance—is incompatible with "actual malice" or "wanton disregard." *E.g.*, *Clark v. Chrysler Corp.*, 436 F.3d 594, 603 (6th Cir. 2006) (finding compliance with National Highway Traffic Safety Administration regulations militated against a finding of malice or reckless disregard sufficient to support punitive damages). Thus, even if the jury ultimately disagrees with Ethicon and the FDA about the safety and risks of Prolift and TVT, FDA evidence is at least relevant to show Ethicon's good faith in designing the devices and writing their respective warnings. *See Hrymoc*, 467 N.J. Super. at 50 (a defendant "may introduce proof of its compliance with federal regulations to demonstrate that it has satisfied its standard of care"). Regardless of precisely what extent the 510(k) process speaks to safety—though, as explained, it speaks *squarely* to safety here—Ethicon's compliance with that regulatory process shows conscientiousness and good faith.

II. STATEMENT OF JURISDICTION

The Court has subject matter jurisdiction under 28 U.S.C. §1132(a) because Plaintiffs are Nevada citizens, Defendants Johnson & Johnson and Ethicon, Inc. are New Jersey citizens, and the amount of in controversy exceeds $75,000, exclusive of interest and costs. Venue is proper under 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to these claims occurred in Nevada.

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III. ADMITTED FACTS THAT REQUIRE NO PROOF

1. On July 23, 2010, Tamara Carter had surgery with Dr. Gregory Hsieh, where he implanted a Prolift device to treat her posterior prolapse (rectocele) and a TVT device to treat her SUI.

2. Prolift is a prescription medical device intended to treat pelvic prolapse in women.

3. TVT is a prescription medical device intended to treat stress urinary incontinence in women.

IV. UNADMITTED FACTS THAT WILL NOT BE CONTESTED AT TRIAL

None.

V. ISSUES OF FACT TO BE TRIED AND DETERMINED AT TRIAL ON THE MERITS

1. Have Plaintiffs proven by a preponderance of the evidence that the warnings for Prolift and/or TVT were inadequate for Dr. Hseih, the implanting surgeon?

2. Have Plaintiffs proven by a preponderance of the evidence that the inadequacies in the warnings caused Mrs. Carter injury?

a. If so, the nature, extent, and amount of Plaintiffs' damages.

3. Have Plaintiffs proven by a preponderance of the evidence that Prolift and/or TVT were unreasonably dangerous and defectively designed?

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4. Have Plaintiffs proven by a preponderance of the evidence that the alleged defects in Prolift and/or TVT caused Mrs. Carter injury?

a. If so, the nature, extent, and amount of Plaintiffs' damages.

5. If liability is established based on any of the grounds stated above, have Plaintiffs proven by clear and convincing evidence that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, or grossly negligent?

a. If so, the amount of punitive damages.

6. Have Defendants proven by the preponderance of the evidence that Tamara Carter assumed the risk of the injuries that she suffered?

Additionally, Defendants believe, and Plaintiffs disagree, that the following are issues of fact to be tried and determined at trial:

1. Were Tamara Carter's injuries, in whole or in part, caused by something other than Prolift or TVT?

2. Did Tamara Carter contribute to her alleged injuries?

VI. ISSUES OF LAW TO BE TRIED AND DETERMINED AT TRIAL

1. Was Prolift unreasonably dangerous and defective in its design, and if so, was this a proximate cause of Tamara Carter's injuries?

2. Was TVT unreasonably dangerous and defective in its design, and if so, was this a proximate cause of Tamara Carter's injuries?

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3. Was Prolift unreasonably dangerous and defective because of its warnings, and if so, was this a proximate cause of Tamara Carter's injuries?

4. Was TVT unreasonably dangerous and defective because of its warnings, and if so, was this a proximate cause of Tamara Carter's injuries?

5. Did Tamara Carter assume the risk of the injuries that she suffered?

6. Have Plaintiffs proved by clear and convincing evidence that Defendants' conduct was malicious, oppressive, willful, wanton, reckless, or grossly negligent under New Jersey law?

7. Is FDA evidence admissible at trial?

8. The parties intend to file motions in limine in accordance with LR 16.3.

Additionally, Defendants believe, and Plaintiffs disagree, that the following are issues of law to be tried and determined at trial:

1. Were Tamara Carter's alleged injuries proximately caused, in whole, or in part, by something other than Prolift or TVT?

2. Did TVT conform to the state-of-the-art at the time of Mrs. Carter's implant on July 23, 2010?

3. Did Prolift conform to the state-of-the-art at the time of Mrs. Carter's implant on July 23, 2010?

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4. Did Tamara Carter knowingly and voluntarily assume all risks associated with TVT and/or Prolift, and thus the "last clear chance" and assumption of the risk doctrines bar in whole or in part the damages that Plaintiffs seek to recover?

5. Is FDA evidence admissible to refute Plaintiffs request for punitive damages?

6. Should Plaintiffs be precluded from presenting evidence that Defendants cannot refute without reference to the FDA?

7. Does the imposition of punitive or exemplary damages violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Nevada Constitution, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States.

8. With respect to Plaintiffs' demand for punitive damages, Defendants specifically incorporate by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries,*

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Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

VII. DEPOSITIONS & EXHIBITS

a) The parties agree to use company witness deposition designations from *Terressa Williams, et al. v. Ethicon, et al.*, Civil Action No. 5:20-cv-00234-MTT (M.D. Ga) (Judge Marc T. Treadwell) for Prolift and *Carolyn Lewis, et al. v Ethicon, et al*, Civil Action No. 2:12-cv-04301 (S.D. W. Va.) (Judge Joseph R. Goodwin) for TVT.[3]

b) Plaintiffs' case specific deposition designations and objections thereto are attached as Exhibit "A".

c) Defendants' case specific deposition designations and objections thereto are attached as Exhibit "B".

d) Per Court order dated March 24, 2022 (ECF 220), the parties shall provide exhibit lists with objections no later than ten (10) after the Court's ruling on motions in limine.

[3] The parties shall meet and confer on two depositions that occurred after the *Lewis* trial (Ms. Angelini, Dr. Weisberg), and Dr. Hinoul's deposition testimony that was not played at the *Lewis* trial.

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e) Electronic Evidence: The parties do not intend on presenting electronic evidence for purposes of jury deliberations.

VIII. WITNESSES THAT MAY BE CALLED BY THE PARTIES AT TRIAL

a) Plaintiffs' Witnesses:

1. Tamara Carter
2. David Carter
3. Adam Carter
4. David M. Carter
5. Eric C. Carter
6. Jason A. Carter
7. Saleha Baig, M.D.
8. Martin Binyange, DNP
9. Gregory C. Hsieh, M.D.
10. Victor Grigoriev, M.D.
11. Christopher Tenggardjaja, M.D.
12. Avi C. Weiss, M.D.
13. Laura Angelini
14. Axel Arnaud, M.D.
15. Thomas Barbolt
16. Peter Cecchini
17. Meng Chen, M.D., Ph.D.
18. Scott Ciarrocca
19. L. Thomas Divilio, M.D.
20. Katrin Elbert, Ph.D.
21. James Hart, M.D.
22. Piet Hinoul, M.D., Ph.D.
23. Kimberly Hunsicker
24. Richard Isenberg, M.D.
25. Scott Jones
26. Gene Kammerer
27. Aaron Kirkemo, M.D.
28. Daniel Lamont
29. Bryan Lisa
30. Vincent Lucente, M.D.

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31. James Mittenthal
32. Sean O'Bryan
33. Charlotte Owens, M.D.
34. Paul Parisi
35. David Robinson, M.D.
36. Renee Selman
37. Jessica Shen, M.D.
38. Daniel Smith
39. Price St. Hilaire
40. Thomas Storozuk
41. Christopher Vailhe, Ph.D.
42. Clifford Volpe
43. Martin Weisberg, M.D.
44. Mark Yale
45. Record Custodians
46. Daniel Elliott, M.D.
47. Prof. Dr. Med. Uwe Klinge, M.D.
48. Bruce Rosenzweig, M.D.
49. Paul Michaels, M.D.
50. R. Brian Raybon, M.D.
51. Dr. Peggy Pence (conditional on admission of FDA/regulatory evidence)

Plaintiffs reserve the right to call any witness on Defendants' witness list.

b) Defendants' Witnesses:

Fact Witnesses

1. Tamara Carter
2. David Carter
3. Adam Carter
4. David M. Carter
5. Eric C. Carter
6. Jason A. Carter
7. Saleha Baig, M.D.
8. Martin Binyange, DNP
9. Gregory C. Hsieh, M.D.
10. Victor Grigoriev, M.D.
11. Christopher Tenggardjaja, M.D.

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12. Avi C. Weiss, M.D.
13. Axel Arnaud, M.D.
14. Thomas Barbolt
15. Scott Ciarrocca
16. Katrin Elbert, Ph.D.
17. Piet Hinoul, M.D., Ph.D.
18. Richard Isenberg, M.D.
19. Vincent Lucente, M.D.
20. Charlotte Owens, M.D.
21. Daniel Smith, Ph.D.
22. Mark Yale
23. Record Custodians

Expert Witnesses

1. Christina Pramudji, M.D.
2. Salil Khandwala, M.D.
3. Juan Carlos Felix, M.D.
4. Steve MacLean, Ph.D. PE
5. Elizabeth Grill, Ph.D.

Defendants reserve the right to call any witness on Plaintiffs' witness list.

IX. DATES ATTORNEYS OR PARTIES OFFER FOR TRIAL

The attorneys have met and jointly offer these three trial dates:

- September 12, 2022 to September 23, 2022
- February 27, 2023 to March 10, 2023
- March 13, 2023 to March 24, 2023

It is expressly understood by the undersigned that the Court will set the trial of this matter on one of the agreed dates if possible; if not, the trial will be set at the convenience of the Court's calendar.

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X. TIME NEEDED

The parties estimate that the trial will take a total of 10 days, equally divided among the parties.

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XI. ACTION BY THE COURT

This case is set for a jury trial on the fixed/stacked calendar off January 30, 2023 at 9:00 a.m. with Calendar call to be held on January 17, 2023 at 9:30 a.m. in courtroom 4A.

DATED: 5/23/2022

UNITED STATES DISTRICT JUDGE

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